Exhibit A - Robert D. Moore, D.O

	Case Name	Civil Action Number
1	Smallridge, Audrey	2:12cv02956
2	Stevens, Kimberly J.	2:12cv02424

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Robert D. Moore, D.O.)

Pending before the court is the Motion to Exclude General-Causation Testimony of Robert D. Moore, D.O. [ECF No. 2119] filed by the defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations

[1] Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 2119-1], which the court has attached to this Memorandum Opinion and Order.

to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by

precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Moore is a board-certified urogynecologist with a subspecialty in female pelvic medicine and reconstructive surgery. Ethicon makes several objections to his proposed testimony, discussed below.

a. Complications

Ethicon challenges Dr. Moore's use of his own studies, which examined various complications associated with polypropylene mesh devices. Ethicon acknowledges that Dr. Moore's studies are the largest, most comprehensive known studies in the world regarding mesh complications. Ethicon argues that these studies are scientifically flawed because they included products *in addition to* the TVT-O, and the studies failed to specifically isolate results that may have been unique to the TVT-O. The studies, however, were not designed with any specific device in mind, but they were developed to examine any potential complications associated with polypropylene mesh implantation. That is exactly what the studies did. I have previously ruled that an expert's method is not unreliable just because a direct comparison study does not exist between devices. *Winebarger v. Bos. Sci. Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *32 (S.D. W. Va. April 24, 2015); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 720 (S.D. W. Va. 2014) ("Ethicon incorrectly asserts that these studies are irrelevant because [Ethicon] did not review the TVT–O specifically."). Ethicon is free to cross-examine Dr. Moore regarding the contours of his studies. Ethicon's Motion is **DENIED** on this point.

Ethicon next argues that Dr. Moore's opinion that the TVT-O causes pain and bladder, bowel, and sexual dysfunction based on a narrative history of the TVT-O is unreliable. The plaintiffs do not respond to Ethicon's Motion regarding Dr. Moore's opinions allegedly based on historical narratives. To the extent that Dr. Moore exclusively bases his opinions on impermissible historical narratives, his opinions are

EXCLUDED. The court offers no ruling with regard to the reliability of Dr. Moore's opinions to the extent his opinions rely on scientific, non-narrative foundations.

Ethicon next argues that Dr. Moore's opinions regarding groin and thigh pain are speculative and should be excluded. Ethicon challenges Dr. Moore's opinion that groin and thigh pain "has been shown to statistically happen more often with [the] transobturator approach" when compared to other approaches such as the retropubic TVT approach. Moore Report 11. Ethicon argues that Dr. Moore premises his opinions on a database review that merely reports statistics and does not give an explanation as to cause. It is important to note, however, that Dr. Moore's report offers opinions regarding the statistical relationship between the incidence of pain and TVT-O implantation. Additionally, Dr. Moore relies on numerous studies that discuss the TVT-O's propensity to cause the complications Dr. Moore discusses. Dr. Moore's opinions are sufficiently reliable under *Daubert*. To the extent that Ethicon believes that Dr. Moore has mischaracterized the findings of the studies he relies on, it may inquire into these topics on cross-examination. Ethicon's Motion regarding Dr. Moore's groin and thigh pain opinions is **DENIED**.

Ethicon next argues that Dr. Moore's opinions regarding chronic leg, pelvic, and nerve pain should be excluded because it is unreliable. Ethicon disagrees with Dr. Moore's interpretation of the significance of a TVT-O study that ultimately had to be discontinued. These arguments are best suited for cross-examination. Ethicon's Motion on this point is **DENIED**.

b. Surgical Technique

First, Ethicon argues that Dr. Moore's opinion about the safety of the surgical technique used to implant the relevant mesh product is unreliable. This opinion, Ethicon claims, is unreliable because Dr. Moore did not account for and ignored contrary literature, specifically a single study mentioned by Ethicon. Upon review, I conclude Dr. Moore adequately explained why she did not find the single study identified by Ethicon particularly compelling. Accordingly, Ethicon's Motion is **DENIED** on this matter. Ethicon is free to further explore this matter on cross-examination.

Second, Ethicon argues that this same opinion is irrelevant. According to Ethicon, the technique used to implant a device plays no role in determining whether a device is defective. The relevance of a matter like this is best assessed in context during trial, so I **RESERVE** ruling on this matter for trial.

c. Safer Alternative Design

Ethicon asks the court to exclude Dr. Moore's expert testimony that Abbrevo was a safer alternative than the device at issue. According to Ethicon, Dr. Moore should not be permitted to offer this testimony because Abbrevo was not a feasible alternative because it was not legally available until July 1, 2010, and because Dr. Moore criticizes the safety of the Abbrevo. But Ethicon does not provide any authority for these propositions. And I do not find their unsupported arguments persuasive. Accordingly, Ethicon's Motion is **DENIED** on this limited issue.

d. Warnings

Ethicon challenges the reliability of Dr. Moore's expert testimony about the adequacy of product warnings, like the relevant Instructions for Use ("IFU"). Specifically, Ethicon challenges the reliability of three aspects of Dr. Moore's expert testimony related to product warnings: (1) that the relevant IFUs should have included information about the frequency, severity, and duration of risks; (2) that other physicians are not aware of the risks Dr. Moore believes should have been included in the relevant IFUs; and (3) that the relevant IFUs should have included a diagram related to patient positioning.

Dr. Moore believes the relevant IFUs should have included information about the frequency, severity, and duration of risks. Ethicon claims this expert testimony is unreliable because Dr. Moore has not identified any resources or materials that support this expert testimony, making it mere *ipse dixit*. I agree and **GRANT** Ethicon's Motion on this point.

The plaintiffs do not address Ethicon's remaining arguments about the reliability of this expert testimony on product warnings. As a result, the plaintiffs have failed to "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). I will not search for evidence that this expert testimony is reliable, nor will I craft arguments for the plaintiffs. Accordingly, I **GRANT** Ethicon's Motion on these points.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard,* 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section

510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with

state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab.*

Litig., 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more

appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude General-Causation Testimony of Robert D. Moore, D.O. [ECF No. 2119].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: September 1, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

LIST OF CASES TO WHICH MOTION TO EXCLUDE GENERAL CAUSATION TESTIMONY OF ROBERT MOORE, D.O. APPLIES*

1. *Angela Coleman, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01267 (TVT-O)
2. *Mary Cone v. Ethicon, Inc., et al.,* Civil Action No. 2:12-cv-00261 (TVT-O)
3. *Teresa Georgilakis, et al. v. Ethicon, Inc., et al*., Civil Action No. 2:12-cv-00829 (TVT-O)
4. *Dawna Hankins v. Ethicon, Inc.*, Civil Action No. 2:12-cv-00369 (TVT-O)
5. *Margaret Kirkpatrick v. Ethicon, Inc., et al*., Civil Action No. 2:12-cv-00746 (TVT-O)
6. *Carrie Smith v. Ethicon, Inc., et al*., Civil Action No. 2:12-cv-00258 (TVT-O)
7. *Isabel Swint v. Ethicon, Inc., et al*., Civil Action No. 2:12-cv-00786 (TVT-O)

* Defendants reserve the right to supplement this list should any plaintiff designate Dr. Moore as a general-causation expert in MDL Wave 1.

Exhibit C

Index of Relevant Pleadings related to Robert Moore, D.O.

Judge Goodwin instituted a series of Waves in MDL 2327 wherein he identified hundreds of cases per Wave subject to discovery and motion practice deadlines. As part of the Wave process, Judge Goodwin required parties to file one general causation *Daubert* motion per expert per Wave in the main MDL, rather than in each individual Wave case. Parties were required to identify the cases in each Wave to which a particular *Daubert* motion applied. The court has identified below, the relevant *Daubert* pleadings filed in each Wave (and in many cases ultimately adopted in subsequent Waves) for the court receiving this case on remand or transfer.

Wave 1	Date	WVSD ECF No.
Motion	5/2/16	2119
Memorandum	5/2/16	2120
Response	5/13/16	2204
Reply	5/27/16	2279
Mem Op & Ord	9/1/16	2715

Wave 2	Date	WVSD ECF No.	Comment
Motion	7/21/16	2459	Adopts ECF No. 2119
Memorandum	7/21/16	2459	Adopts ECF No. 2120
Response	8/8/16	2520	Adopts ECF No. 2204
Reply	8/18/16	2577	Adopts ECF No. 2279
Mem Op & Ord	3/27/17	3509	Adopts ECF No. 2715

Wave 3	Date	WVSD ECF No.	Comment
Motion	12/22/16	3290	Adopts ECF No. 2119
Memorandum	12/22/16	3290	Adopts ECF No. 2120
Response	1/3/2017	3304	Adopts ECF No. 2204
Reply			